

AUG 11 2006

**510(k) Summary of Safety and Effectiveness for the
Triathlon® Metal Backed Patella**

Proprietary Name:	Triathlon Metal Backed Patella
Common Name:	Total Knee Joint Replacement Prosthesis
Classification Name and Reference	Knee Joint; Patellofemorotibial; Metal/polymer; Porous-coated; Uncemented prosthesis 21 CFR §888.3565
Regulatory Class:	Class II
Device Product Code:	87 MBH - prosthesis, knee, patello/femorotibial, semi-constrained, uncemented, porous, coated, polymer/metal/polymer.
For Information contact:	Tiffani Rogers Regulatory Affairs Specialist Stryker Orthopaedics 325 Corporate Drive Mahwah, New Jersey 07432 Phone: (201) 831-5412 Fax: (201) 831-6038 E-Mail: Tiffani.Rogers@stryker.com
Date Summary Prepared:	June 1, 2006

Device Description

The Triathlon® Metal Backed Patella is designed to offer patellar resurfacing when needed with the Duracon® or Triathlon® Total Knee Systems. The subject metal-backed patella is available in four sizes designed to fit the peripheral shape of the resected patella. The posterior surface of the patella features a porous coated metal back, with a preassembled polyethylene anterior surface.

Intended Use:

The metal backed patella is intended for patellar resurfacing to alleviate pain, instability and the restriction of motion.

Indications for Use

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The Triathlon® Total Knee System components included in this submission are intended for use in total knee arthroplasty to relieve pain and restore knee functions for indications such as:

- Noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis or avascular necrosis;
- Rheumatoid arthritis;
- Correction of functional deformity;
- Revision procedures where other treatments or devices have failed;
- Post traumatic loss of joint anatomy, particularly when there is patello-femoral erosion, dysfunction or prior patellectomy; and,
- Irreparable fracture of the knee.

These products are intended to achieve fixation without the use of bone cement.

Substantial Equivalence:

The metal-backed patella is substantially equivalent to Howmedica Osteonics' Duracon metal-backed patella cleared in K032418. Each device is similar in design, and has the same indications, intended use, and sterilization.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 11 2006

Howmedica Osteonics Corp.
% Ms. Tiffani Rogers
Regulatory Affairs Specialist
325 Corporate Drive
Mahwah, New Jersey 07432

Re: K061521

Trade/Device Name: Triathlon[®] Metal Backed Patella
Regulation Number: 21 CFR 888.3565
Regulation Name: Knee joint patellofemorotibial metal/polymer porous-coated
uncemented prosthesis
Regulatory Class: Class II
Product Code: MBH
Dated: June 1, 2006
Received: July 12, 2006

Dear Ms. Rogers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

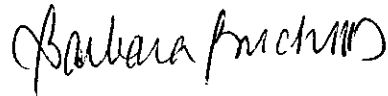
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA

Page 2 - Ms. Tiffani Rogers

finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson".

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: Triathlon® Metal Backed Patella

Indications for Use

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- Irreparable fracture of the knee.

These products are intended to achieve fixation without the use of bone cement.

Prescription Use X

OR
(Per 21 CFR 801.109)

Over-the-Counter Use _____

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) *Barbara Brehm*
Division of General, Restorative,
and Neurological Devices

510(k) Number K061521